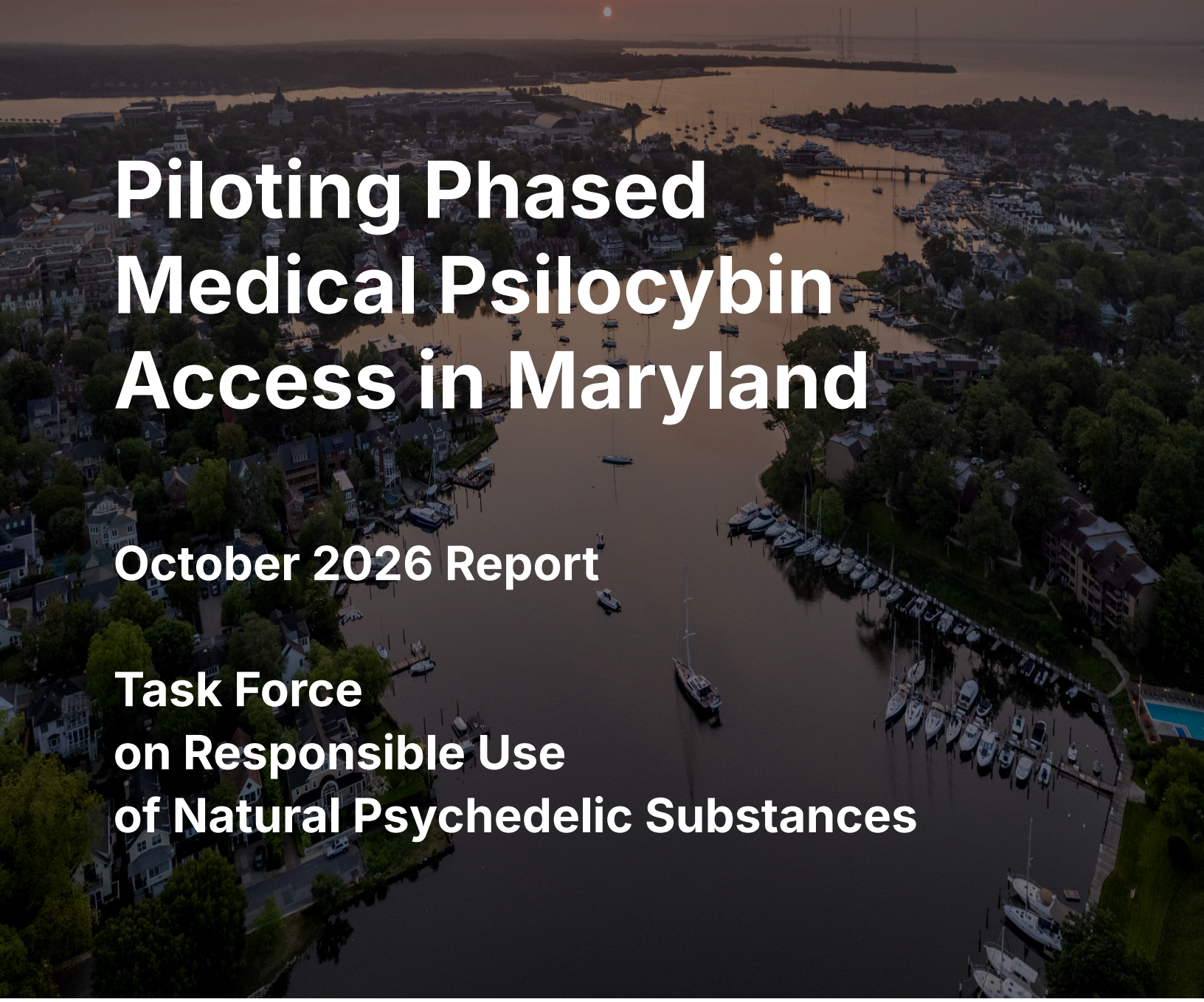


Piloting Phased Medical Psilocybin Access in Maryland

October 2026 Report

Task Force on Responsible Use of Natural Psychedelic Substances

MCA
MARYLAND
CANNABIS
ADMINISTRATION

Chapters 792 & 793 of 2024 establish the Maryland Task Force on Responsible Use of Natural Psychedelic Substances, staffed by the Maryland Cannabis Administration. Chapters 207 & 208 of 2026 updated Task Force membership. The Task Force is charged with studying existing laws, policies, practices, and data relating to the use of naturally derived (plants/fungi) psilocybin/psilocin, dimethyltryptamine (DMT) , and mescaline; and making legislative recommendations which may involve access to regulated treatment, public education, safe production, and criminal deprioritization.

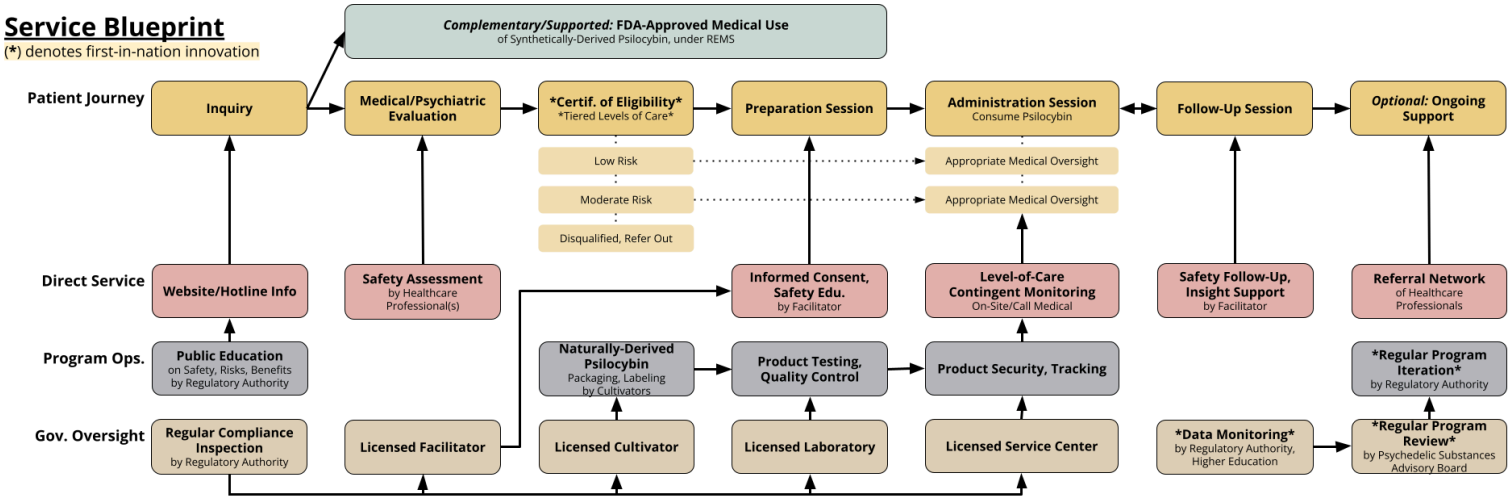
Executive Summary

The Task Force recommends a state-regulated Medical Psilocybin Access Program, with modular infrastructure designed to support clinical use, extraclinical use, and anticipated FDA approval with unified safety and data monitoring.

- **Oregon, Colorado, and New Mexico have established psilocybin programs**, providing valuable models.
- Researchers at Johns Hopkins University and other institutions have found that, when administered under certain supervised conditions, **psilocybin can reduce symptoms of depression and other medical conditions**. Patients commonly report temporary, mild-to-moderate adverse effects, while serious adverse events remain uncommon.
- With **Maryland's world-leadership in psychedelic science** and public health, the state is well-positioned to **set the standard for national policy** while addressing local needs and minimizing existing unregulated markets.
- Veterans face elevated rates of PTSD, depression, and chronic pain. A state-regulated program could provide **substantial public benefit** by expanding safe access to professionally supervised treatment for this population.

Program Highlights, (*****) denotes first-in-nation innovation:

- **State Oversight:** To be regulated by Maryland Cannabis and Psychedelic Administration (replacing the Maryland Cannabis Administration) to ensure strict safety, quality control, and compliance.
- **Patient Eligibility:** Limited to adults with specific medical conditions, determined through clinical evaluation.
- ***Tiered Medical Certification*:** Comprehensive risk screening assigns patients to levels of care, with corresponding controls, treatment protocols, and medical oversight.
- **Safety Protocols:** Mandatory pre-session screening, supervised administration by state-licensed facilitators in controlled clinical settings, and follow-up care.
- **Supply Chain & Quality Control:** State-licensed cultivation and lab testing for all natural psilocybin, with flexibility to include FDA-approved synthetic derivatives.
- ***Data-Driven Program Iteration*:** Real-time tracking of health outcomes, adverse events, population-level data, and scientific evidence to inform updates to screening algorithms and clinical protocols.
- **Equitable Access for Veterans and Underserved Populations:** Measures to reduce barriers for eligible veterans, first responders, individuals with disabilities, rural residents, low-income patients, and other underserved populations, while maintaining medical eligibility and patient safety standards.



See full October 2026 Report below for Base Statutory Language and Recommended Provisions

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Psilocybin Science & Policy Brief



Psilocybin and Psilocin

Found in Several Species of Fungi

Overview

- **Non-addictive**
- **No established lethal dose**
- Onset (oral): 20-60 min
- Duration: 4-6 hr
- Effects: Altered perception, emotion, cognition, sense of self, time; modulated by expectations, dose, physical/social environment ("set/setting")
- **1 in 8 (12.1%) U.S. adults tried psilocybin**[1]
- Older adults' use increased 188%, 2019-2023[2]
- Naturalistic consumption infrequent: 1-2 days/year[1]
- Motives: mental health (48.8%), personal development (45.2%), spiritual growth (41.3%)[1]

⚠️ Risks

Acute:

- Psychological distress
- Headache, nausea, dizziness, fatigue
- Transient, low-level blood pressure and heart rate increase
- Accidental injury by impaired judgment
- Vulnerable, suggestible state
- Risks with poly-substance use

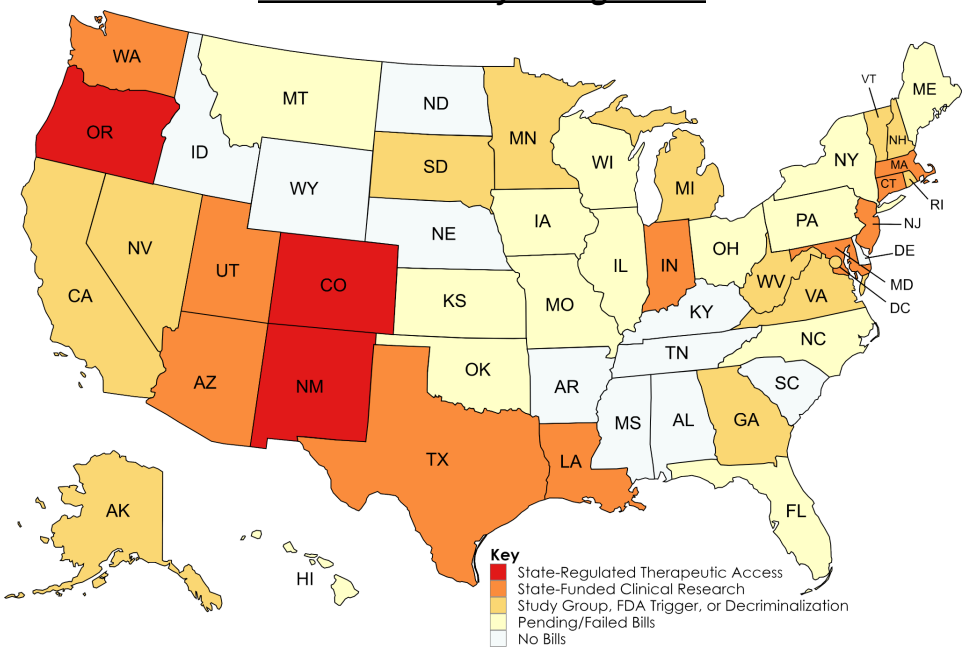
Uncommon:

- Seizure
- Persistent perceptions (HPPD)
- Mania/psychosis in susceptible individuals
- Suicidal ideation, self-injury

✅ Benefits

- **Clinical Trial Efficacy:** Significant and durable symptom reduction in Major Depression (including treatment-resistant cases), PTSD, Substance Use (alcohol/nicotine), and End-of-Life Anxiety
- **Emerging Indications:** Preliminary evidence for Cluster Headaches, Cognitive Decline, and Eating Disorders
- **Non-Clinical & Spiritual Value:** Enhanced personal growth and deepened faith in religious settings

Nationwide Psilocybin Legislation



Federal

- FDA "Breakthrough Therapy"
- DoD Research
- Exec. Order: Apr. 2026 "Accelerating Medical Treatments"
- Schedule 1 Drug (Most Restricted)
- Rescheduling anticipated Jan. 2027

Other States

- 3 Existing state-regulated programs
- Oregon: 20,000+ served, <0.2% (32) emergency reports
- DC: Unregulated gray-market

Maryland

- World-renowned Johns Hopkins Psychedelic Research Center
- 6 Major institutions in-state
- Psychedelic science leader since 1960s

The Task Force recommends a Maryland state-regulated program to:

📈 **Maximize Public Benefit:** Healthcare Cost Savings, Equitable Scalability, Health Outcomes, Real-World Safety Monitoring, Evidence-Based Policy, Industry & Ancillary Job Creation, Modest Tax Revenue

🛡️ **Mitigate Public Risk:** Supply Chain Safety, Public Health Education, Licensed Facilitator Oversight, Unified Safety Standards for Clinical & Extraclinical Treatment

For details and references, see October 2025 Report via Department of Legislative Services Library or Task Force member-hosted MarylandNPS.org

Psilocybin Science & Policy Brief, References

[1] Kilmer, B., Priest, M., Ramchand, R., Rogers, R. C., Senator, B., & Palmer, K. (2024). Considering alternatives to psychedelic drug prohibition. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA2825-1.html

[2] Rockhill, K. M., Black, J. C., Ladka, M. S., Sumbundu, K. B., Olsen, H. A., Jewell, J. S., Hunt, J., Wolf, R. C., Nerurkar, K., Dart, R. C., & Monte, A. A. (2025). The rise of psilocybin use in the United States: A multisource observational study. Annals of Internal Medicine, 178(7), 1052–1054. https://doi.org/10.7326/ANNALS-24-03145

[3] Task Force on Responsible Use of Natural Psychedelic Substances. (2025). Maryland Natural Psychedelic Substance Access Program: A Pathway Forward. Available at: https://marylandmatters.org/wp-content/uploads/2025/11/Ch793Ch7922024_202510.pdf.

Recommendation: Medical Psilocybin Access Program

Established through legislation passed unanimously with bipartisan support, the Task Force develops evidence-based, equity-focused policy recommendations with support from the Maryland Cannabis Administration. The Task Force has brought together vetted experts in medicine, public health, law enforcement, and spirituality, and draws on the expertise of national leaders in psychedelic science at Johns Hopkins University and the University System of Maryland. Since convening in 2024, Task Force members have contributed 900+ hours of service.

In its first year,the Task Force conducted a scientific literature review, consulted subject-matter experts, and engaged state agencies, national industry leaders, and local constituents through statewide public listening sessions and written comments. Additionally, the Task Force examined emerging psychedelic policies in Washington, D.C., Oregon, Colorado, New Mexico, and other jurisdictions, drawing valuable lessons from their innovations, successes, and implementation challenges. To analyze the merits and risks of various access frameworks, the Task Force employed a rigorous, consensus-based, modified-Delphi methodology, ultimately converging on 59 “Strongly Recommended” policy propositions.

The July 2025 Report provided interim findings. The October 2025 Report superseded the prior report, with comprehensive study findings and recommendations. Study findings included ethnobotanical, biochemical, and pharmacological monographs; a comparison of use practices; research evidence across indications; public perceptions; and other data. Studies identified opportunities for Maryland to maximize public benefits and mitigate public risks. Recommendations included a full list of the Task Force’s modified-Delphi consensus ratings; summary of deliberations; and a proposed comprehensive framework toward state-regulated psychedelic access, with phased implementation. An independent team of economists at Johns Hopkins University analyzed the impact of our recommendations and described how including both traditional and novel metrics may better reflect the social implications of reform, offering data-evaluation and program-iteration mechanisms to include at the outset.

The following is a concise and psilocybin-specific presentation of the Task Force’s recommendations on a pilot phased medical access program for Maryland.

DEFINITIONS	
Base Statutory Language	**Recommended Provisions**

• **"Psilocybin"** means psilocybin, psilocin, and related psychoactive alkaloid compounds, whether naturally occurring or synthetically derived, including:
  ○ The whole fruiting-body, or any part, preparation, mixture, or derivative thereof, of any fungal species belonging to the genus Psilocybe or other psilocybin-containing fungi; and
  ○ Any synthetic chemical compound, purified molecule, drug product, or pharmaceutical formulation, including any FDA-approved medicine, containing psilocybin or psilocin.
• **"Natural Psychedelic Substance"** means naturally derived psilocybin, psilocin, dimethyltryptamine (DMT), and mescaline except peyote.
• **"Service Site"** means a facility licensed by the state for storage of psilocybin products and the provision of psilocybin administration under appropriate medical oversight, and may include a state-licensed healthcare facility, clinic, or specialized non-clinical setting.
• **"Facilitator"** means an individual trained, credentialed, and licensed to conduct psilocybin preparation sessions, administration sessions, and follow-up sessions.
• **"Health Screening"** means a mandatory, pre-administration consultation wherein a licensed medical provider assesses a patient's eligibility for the program.
• **"Preparation Session(s)"** means one or more mandatory, pre-administration consultations wherein a licensed facilitator explains the established safety protocols, obtains informed consent, and provides counseling and planning regarding the specific objectives of treatment to patients who intend to receive psilocybin.
• **"Administration Session"** means a supervised period during which an eligible patient ingests psilocybin under continuous or near continuous monitoring and direct care of a facilitator in an environment that complies with the requirements to ensure physiological and psychological safety.
	See October 2025 Report, propositions: 1a, 2a, 63a, 67a, 77a, 84a

DEFINITIONS	
• **"Follow-Up Session(s)"** means one or more post-administration consultations wherein a licensed facilitator assists the patient who has received psilocybin in identifying experiences from the administration in the furtherance of the treatment; assessing and processing any adverse events; and reviewing or critiquing procedures and safety protocols. Follow-Up Session(s) may include "integration" psychotherapy, where appropriate.	

• **"Patient"** means an individual at least 18 years of age who, within a bona fide provider-patient relationship, has obtained written certification from a licensed healthcare provider confirming that the individual is a medically appropriate candidate for psilocybin use based on the presence of applicable inclusionary criteria and the absence of applicable exclusionary criteria. Medical appropriateness does not require a diagnosis under the Diagnostic and Statistical Manual of Mental Disorders (DSM).	**Considerations:**
	• …and with a qualifying condition.
	• "Qualifying condition" includes:
	  ◦ Post-Traumatic Stress Disorder (PTSD)
	  ◦ Major Depressive Disorder (MDD)
	  ◦ Substance use disorders
	  ◦ Anxiety disorders
	  ◦ End-of-life distress
	  ◦ and other conditions as approved by the Regulatory Authority, based on scientific evidence
	
	See <u>October 2025 Report</u>, propositions: 2a, 4a, 67a, 84a, 5c, 78c

ESTABLISHMENT OF A PSYCHEDELIC SUBSTANCES ADVISORY BOARD	
Base Statutory Language	**Recommended Provisions**
● A Psychedelic Substances Advisory Board shall be established.	**Considerations:** ● The Advisory Board consists of the following members, appointed by the Governor with the advice and consent of the House and Senate: ○ one member of the Senate of Maryland who shall be appointed by the President of the Senate ○ one member of the House of Delegates who shall be appointed by the Speaker of the House ○ the Secretary of the Department of Health, or the Secretary's designee ○ the Secretary of the Department of Disabilities, or the Secretary's designee ○ the Secretary of the Department of Veterans and Military Families, or the Secretary's designee ○ the Director of the Maryland Cannabis and Psychedelic Administration, or the Director's designee ○ one or more representatives from the University System of Maryland, the Johns Hopkins University's Center for Psychedelic and Consciousness Research, or Sheppard Pratt ○ one representative of a Historically Black College or University in the State ○ one individual with experience in the religious or spiritual use of psychedelic substances ○ one individual with experience in the traditional indigenous use of psychedelic substances ○ one individual with expertise in behavioral health ○ one individual with expertise in the treatment of substance use disorders ○ one individual with expertise in the treatment of chronic pain ○ one individual with expertise in psychedelic–assisted psychotherapy ○ one individual with expertise in psychedelic research ○ one individual with expertise in access to care in underserved communities ○ one individual with expertise in drug policy reform

ESTABLISHMENT OF A PSYCHEDELIC SUBSTANCES ADVISORY BOARD	
	○ one individual with expertise as a member of law enforcement ○ one individual who is a patient with mental health conditions that can be treated with psychedelic substances ○ one individual who is a patient with a recognized, clinically verified chronic pain conditions that can be treated with psychedelic substances ○ one individual who is a patient with palliative care conditions that can be treated with psychedelic substances ○ one individual with expertise with the pharmacology of psilocybin ○ one physician with experience with the appropriate use of psychedelic substances and other integrative medical practices ○ one individual with expertise in healthcare economics ● A majority of the members constitutes a quorum, and a quorum of the members present and a majority vote are needed to take any action. ● The Governor shall designate the chair of the Advisory Board. ● The term of a member of the Advisory Board is 4 years. ○ At the end of a term, a member continues to serve until a successor is appointed and qualifies. ○ An appointed member may not serve more than two full terms. ● An appointed member of the Advisory Board must be: ○ a resident of Maryland who has resided in the State for at least 5 years immediately preceding the appointment. ● To the extent practicable and consistent with federal and State law, the membership of the Advisory Board shall reflect the racial, ethnic, and gender diversity of the State. ● The Regulatory Authority for the establishment of a Medical Psilocybin Access Program shall provide staff for the Advisory Board. ● The Regulatory Authority may establish an Independent Consumer Advisory Board composed of Medical Psilocybin Access Program participants, for the purpose of ensuring participant-led advice and eliminating barriers to membership by providing members with stipends, transportation support, technology assistance, and reasonable accommodations.

ESTABLISHMENT OF A PSYCHEDELIC SUBSTANCES ADVISORY BOARD	
	See October 2025 Report, propositions: 10a
● The Psychedelic Substances Advisory Board shall: ○ Consider all matters submitted to it by the Governor, the General Assembly, the Office of Social Equity, or the Regulatory Authority for the Medical Psilocybin Access Program	**Considerations:** ● The Psychedelic Substances Advisory Board shall: ○ Assist the Regulatory Authority in establishing initial regulations for the Medical Psilocybin Access Program. ○ Advise the Department of Health, Office of Controlled Substances, and any other relevant state agencies on implementation of FDA-approved psilocybin medicine. ○ Study emerging research, implementation outcomes, stakeholder feedback, developments in other jurisdictions, and developments with Federal scheduling. ○ Accept and review public petitions for adjustments to the Medical Psilocybin Access Program. ○ Make recommendations regarding eligibility criteria, best practices, dosing standards, licensing requirements, safety and training standards, and data collection, methods to ensure there is adequate supply of affordable products and services for qualifying patients, methods to ensure economic sustainability of the program, public health, public safety, equitable access including for low-income and rural residents, and any other matter relevant to the operation of the program. ○ Submit an annual report to the Regulatory Authority for the Medical Psilocybin Access Program on findings and recommended program adjustments by December 31st. ○ Convene a minimum of 4 times per year for public hearings, to evaluate public petitions, and conduct other business. **See October 2025 Report, propositions:** 10a, 84a, 7b

ESTABLISHMENT OF A PSYCHEDELIC SUBSTANCES ADVISORY BOARD	
• The Psychedelic Substances Advisory Board may: ○ Use interviews with stakeholders and ethnographic reporting of subjects to supplement objective data reporting.	
• The members of the Task Force on Responsible Use of Natural Psychedelic Substances as of the effective date of this Act, including ex-officio members and members appointed by the Governor, shall become initial members of the Psychedelic Substances Advisory Board as established under this Act, until individually replaced by the Governor.	

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
Base Statutory Language	**Recommended Provisions**
● A Regulatory Authority shall be established.	**Considerations:** ● The Maryland Cannabis Administration shall be renamed as the Maryland Cannabis and Psychedelic Administration.
● The Regulatory Authority shall	
○ Establish licensing standards for:	
■ Psilocybin Cultivators	**See October 2025 Report, propositions:** 44a
■ Psilocybin Testing Laboratories	**Considerations:** ● The Regulatory Authority shall determine how to most efficiently and cost effectively structure the product testing process, and whether the testing facilities are operated by the State, by an independent licensed entity, or both state and independent facilities.
■ Psilocybin Service Sites	**See October 2025 Report, propositions:** 63a
■ Psilocybin Facilitators	
	Strongly Recommended: ● Procedures for issuing licenses shall be designed to provide a diverse participation among licensees, reflecting the population of Maryland. ● To the greatest extent practicable, qualified applicants who are members of groups that have been disproportionately adversely impacted by drug laws in force from 1973 to 2023 shall be enabled to obtain licenses. ● Licensees shall be subject to regular inspection by the appropriate regulatory authority for compliance with rules and regulations established under this title.

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	Considerations: ● If the number of licenses is limited, the Regulatory Authority shall establish a pre-qualification review process to identify applicants that meet the minimum operational and threshold requirements. Applicants determined to be qualified through this initial review shall be eligible to participate in an application lottery for the available licenses. **See <u>October 2025 Report</u>, propositions:** 18a, 75a
○ Promulgate regulations establishing minimum standards and operational requirements for:	
■ Cultivation	**Strongly Recommended:** ● Cultivation standards shall include measures to reduce risk of diversion. ● Cultivation standards shall minimize adverse environmental impacts. ● Cultivation standards shall assure that products are free of any chemical, heavy metal, fungal, or other contamination as determined by routine testing. **Considerations:** ● Licensees shall be limited to producing for distribution whole, dried psilocybin mushrooms. ● Production of any extracts, infused products, genetically modified species, etc. shall remain illicit under this title. ● The Regulatory Authority may develop production targets or quotas (generally and for individual licencees) to reduce the risk of oversupply or undersupply limiting adequate access (due to unnecessarily high prices or unprofitability that removes appropriate competition). **See <u>October 2025 Report</u>, propositions:** 1a, 17a, 51a

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
■ Product Packaging	**Strongly Recommended:** ● Product packaging shall bear standardized warning labels. ● Product packaging shall be child-proof and pet-proof. ● Product content shall conform to the standardized dosage and described on the package. ● Product packaging shall include labeling adequately complete and legible to describe contents of the package and safety risks associated with consuming the product. **Considerations:** ● The Regulatory Authority may utilize the International Psychedelics Product Symbol (IPPS), which is compliant with ISO 3864 and ANSI Z535 standards. ● To reduce the risk of unintended overconsumption, dosage units shall be standardized such that the average patient must consume more than one dosage unit in order to attain a hallucinogenic effect. **See <u>October 2025 Report,</u> propositions:** 48a, 49a
■ Product Tracking	**Strongly Recommended:** ● The regulations under this subparagraph shall include transaction documentation requirements for licensed entities, regarding the source, complete product description, price paid for each shipment received for its inventory, and the quantity distributed. Records must be preserved for inspection by the administration for 2 years after the transaction. **Considerations:** ● The Regulatory Authority shall implement an electronic tracking system and secure transportation protocols for psilocybin transferred between and among licensed cultivators, processors, testing laboratories, medical staff, facilitators, and authorized facilities.

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	See October 2025 Report, propositions: 52a, 38c
■ Quality Control	**Strongly Recommended:** ● The regulations under this subparagraph shall include standards for purity, potency, and concentration of psilocybin, requirement for testing for materials to comply with established standards, and mechanisms for assuring compliance with purity, potency, and concentration standards. ● The regulations under this subparagraph shall provide that psilocybin product not tested in a state-licensed laboratory and meeting standards for purity, potency, and concentration, or without the results printed on the labeling or otherwise readily available to consumers and health practitioners, may not be dispensed or distributed by any licensee. **See October 2025 Report, propositions:** 46a
■ Health Screening and Eligibility	**Strongly Recommended:** ● The Regulatory Authority shall develop tiered risk-based levels of care, including at minimum, but not limited to the following levels of care: (a) low risk of medical and/or psychiatric complications, (b) moderate risk of medical and/or psychiatric complications, or (c) disqualified from the program. ● Medical and psychiatric screening for eligibility shall require that, prior to any administration sessions, all persons are screened by appropriate licensed healthcare professional(s) for placement in one of the risk-based levels of care. ● A licensed facilitator may adjust a patient's assigned level of care, based on updated medical and psychiatric screening, or other legitimate health changes, to best reflect the patient's updated health information at the time of administration. ● The Regulatory Authority may designate additional risk-based levels of care. ● The Regulatory Authority may expand qualifying conditions and eligibility criteria based on emerging scientific evidence. ● The Regulatory Authority shall determine safety and supervisory

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	requirements/restrictions and alternative care options which correlate to identified risk-based levels of care. ● The Regulatory Authority may determine appropriate criteria to exclude persons from participating in psilocybin administration, as well as a method for re-evaluation by a second healthcare provider if an appeal is requested. ● The Regulatory Authority shall determine what healthcare providers acting within the scope of their practice are qualified to sufficiently assess eligibility criteria. ● In determining what pre-requisite training and the type of healthcare provider qualified to assess eligibility criteria, the Regulatory Authority may consider licensed physicians, nurse practitioners, physician assistants, psychologists, clinical social workers, and licensed clinical professional counselors. **See October 2025 Report, propositions:** 2a, 67a, 79a, 5c, 78c
■ Veteran Access	**Considerations:** ● The Regulatory Authority shall ensure that veterans have convenient, low-cost treatment under this program if recommended by their health care provider, including reduced patient certification fees and sliding-scale service fees. ● The Regulatory Authority may request appropriations from the State of Maryland to subsidize the costs of treatment and determine eligibility criteria for veterans to receive such subsidies. ● Public education shall include veteran-specific materials, developed with veterans service organizations, addressing how participation in a state-regulated program relates to federal law and to VA care and benefits. ● Data collected under this program shall include de-identified veteran status, so that outcomes for veterans can be reported and shared with federal research partners. **See October 2025 Report,** Special Populations of Interest - Serving Those Who Served, pp. 152–153, and Medical/Therapeutic Use Pathway, pp. 242

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
■ Equitable and Affordable Access	**Strongly Recommended:** ● The Regulatory Authority shall establish programs that incentivize service sites to ensure equitable and affordable access, such as sliding-scale fee structures or patient discount programs in exchange for reduced training, certification, or licensing fees. ● The Regulatory Authority may request appropriations from the State of Maryland to subsidize the costs of treatment and determine eligibility criteria for patients to receive such subsidies. **Considerations:** ● A treatment equity fund, supported by a portion of licensing fees and program revenue, may subsidize care for patients who cannot afford it. ● In issuing licenses, the Regulatory Authority shall consider the availability of service sites in rural and underserved counties. ● The Regulatory Authority shall establish programs that reduce or waive certification fees for low-income patients. **See October 2025 Report, propositions:** 18a, 74a, 7b
● Written Certification of Patient Eligibility and Identification	**Considerations:** ● The Regulatory Authority may require the issuance of identification numbers or cards, to licensees and to patients upon certification of eligibility. **See October 2025 Report, propositions:** 4a, 5c, 6c
■ Patient Education and Informed Consent	**Strongly Recommended:** ● The Regulatory Authority may establish requirements for a prerequisite patient education in plain-language, and adaptable to meet a range of ability levels, for the purpose of patient education. Such education shall be available at no or negligible cost to the patient. The Regulatory Authority may require minimum knowledge requirements for eligible patients. Patients should be

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	notified that information about them and their treatment will be obtained by the Regulatory Authority and retained and used for research purposes by the Regulatory Authority and researchers it authorizes. ● The Regulatory Authority shall promulgate an informed-consent process, requiring that all patients be provided with appropriate education about the risks, benefits, and alternatives to the facilitation process and to the administration of psilocybin, including any warnings if necessary, *prior* to the administration of psilocybin. Educational materials shall be available in plain-language, offered in best-match languages other than English, and accessible across a broad range of needs, for the purpose of ensuring informed consent and safer use. ● In addition, educational materials shall be provided to all individuals at the time of receiving psilocybin. After written materials and an oral explanation have been provided, patient consent shall be obtained again in writing. ● Consent by each patient shall be documented and preserved for at least two years following administration. ● No licensee may make any representation that indicates psilocybin will relieve, treat, diagnose, or prevent health conditions or any other ailment unless the claim is substantiated by competent and reliable scientific evidence. The Regulatory Authority may mandate the immediate retraction of unsubstantiated claims and penalize non-compliant licensees. ● Marketing of psilocybin may not in any way target minors. ● The Administration shall review any claims of misconduct, reports of any violation of regulations committed by any person whether or not a licensee, may investigate on its own any suspicion of violation and recommend penalties based on their findings, including revocation or suspension of this license or any license otherwise granted by the State Professional Boards, or refer cases to the appropriate prosecutorial authority. **See October 2025 Report, propositions:** 13a, 47a, 50a, 76a, 80a

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
■ Facilitator Education and Training	**Strongly Recommended:** ● The Regulatory Authority shall determine minimum training requirements of licensees to protect the safety of the persons consuming psilocybin under supervision. ● In collaboration with the professional boards of licensure, the Regulatory Authority shall establish dual-licensure permissions that allow participation by licensed health care providers acting consistent with the scope of their professional practice. ● To the extent practicable, the Regulatory Authority shall establish low-cost, accessible training options for potential licensees or others for whom training is mandated sufficient to satisfy the training mandate. **See October 2025 Report, propositions:** 19a, 65a, 66a, 77a
■ Facilitation and Safety Standards	**Strongly Recommended:** ● The Regulatory Authority shall establish standards for psilocybin administration settings, for staffing by licensed psilocybin facilitators, for minimum staff-to-consumer ratios for various services, for mandatory safety equipment, for mandatory training in required safety protocols, for standards for the practice of psilocybin facilitation, for accessibility for patients with disabilities, for patients receiving palliative care, and for patients for whom chronic pain presents a significant barrier to access. ● The regulations shall require that all patients undergo a preparation session prior to the first administration session. ● The regulations under this subparagraph may require a follow-up session following the administration session, contingent on risk-based level of care. ● The Regulatory Authority shall establish a system to facilitate the reporting to it of violations of regulations, or any practice creating a risk of danger, abuse, or harm, and to protect from retaliation those persons who make such reports to the Regulatory Authority or any other appropriate agency.

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	See October 2025 Report, propositions: 11a, 64a, 68a, 69a, 70a, 71a, 72a, 81a, 89
■ Law Enforcement Training	**Strongly Recommended:** ● The Regulatory Authority, in collaboration with The Maryland Police and Correctional Training Commissions, shall establish training requirements and timetables for implementation of training for law enforcement and correctional agencies regarding ○ the laws regarding psilocybin; and ○ the integration of appropriate mental health and crisis responders with law enforcement first responders to incidents that appear to be related to the use of psilocybin. ● The Regulatory Authority, in collaboration with The Maryland Police and Correctional Training Commissions and the Maryland State Police, shall identify opportunities to track with more specificity the specific substances associated with arrests and violations of the Controlled Dangerous Substances Act, at minimum differentiating natural psychedelic substances from synthetic in each instance. **See October 2025 Report, propositions:** 28a, 90a
■ Research and Data Monitoring	● The Regulatory Authority shall establish systems to collect county-level data sufficient to evaluate all aspects of the production, distribution and use of psilocybin including economics of the market, state revenues, program integrity, prevalence and frequency of use, modes of use, services rendered and modality (e.g. telehealth follow-up), safety and adverse events, clinical outcomes of persons included and excluded from the program, crimes associated with psilocybin, public health outcomes, occupational health, access, and social equity impact. ● The Regulatory Authority shall establish and maintain an accessible mechanism, including an electronic portal, for patients to self-report adverse events experienced during or after a supervised session.

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	● The regulations under this subparagraph shall require service sites to: ○ Collect and maintain patient de-identified data on dosages administered, patient outcomes, and adverse events for all patients and administrations of psilocybin; ○ Report to the Regulatory Authority, upon request, such data, and any other information relevant to adverse events, investigation of violations of regulations or laws, or professional misconduct. ● Unless for investigative purposes and upon the issuance of a judicial warrant meeting the standards for issuance of a search warrant, data collected and disseminated by the Regulatory Authority shall exclude personally identifying information about individual consumers of psilocybin. ● The Regulatory Authority shall provide the public with data presentations explaining the functioning of the program, updated a least twice per year. ● The Regulatory Authority may partner with Maryland universities, hospitals, and other state and local agencies to conduct research. ● The Regulatory Authority may establish programs that incentivize the comparative study of psychedelic use across Western-medicine and naturalistic contexts. **See <u>October 2025 Report</u>, propositions:** 15a, 16a, 73a, 87
■ Public Education	**Strongly Recommended:** ● The Regulatory Authority shall educate the public about the legal status, potential risks and benefits, and practices that promote safer psilocybin use. **See <u>October 2025 Report</u>, propositions:** 12a, 30a
● In proposing rules and regulations, the Regulatory Authority shall conduct public listening sessions and provide a mechanism for public comment and review	

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
such comments before adopting final regulations.	
● In establishing rules and regulations, the Regulatory Authority may consult: ○ The Task Force on Responsible Use of Natural Psychedelic Substances ○ The Psychedelic Substances Advisory Board. ○ Persons and parties with relevant knowledge and expertise, including but not limited to other jurisdictions with enacted psychedelic access models, higher education institutions, healthcare providers, and the cannabis industry in Maryland.	
● The Regulatory Authority shall implement a regular policy review process, due no less frequently than annually by December 31st, to: ○ Review ■ Outcome data from program implementation. ■ Recommended program adjustments submitted by the Psychedelic Substances Advisory Board. ■ Programs of a similar character in other states or	**See <u>October 2025 Report</u>, propositions:** 20a, 41, 43a, 45a, 57a, 59a, 62a, 34b, 55b, 56b

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
nations. ○ Review, and if appropriate, amend regulations to ensure, to the greatest extent practicable: ■ Best practices are employed. ■ Access to the program is equitable and affordable. ■ Populations with potential to benefit are served by the program. ■ Identified responsible uses of psilocybin are served by the program. ■ Public risk regarding psilocybin use is mitigated.	
● In implementing regular policy review process, the Regulatory Authority may consult: ○ The Task Force on Responsible Use of Natural Psychedelic Substances. ○ The Psychedelic Substances Advisory Board. ○ Persons and parties with relevant knowledge and expertise, including but not limited to other jurisdictions with enacted psychedelic access models, higher education institutions, healthcare providers, and the cannabis industry in Maryland.	

ESTABLISHMENT OF A STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
• The Regulatory Authority may employ staff and retain contractors as provided in the State budget. • Nothing in this Act authorizes the sale, transfer, administration, production, marketing, or distribution of psilocybin, except as provided for by this Act or other state or federal law.	

ENFORCEMENT OF THE STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
Base Statutory Language	**Recommended Provisions**

• Rename the Alcoholic Beverages and Cannabis Article of the Code of Maryland as the Sensitive Consumer Substances Article.
• The Commission shall:
  ○ carry out public health and safety measures relating to alcohol, tobacco, cannabis, and psilocybin.
  ○ regulate the manufacture, commercial distribution, transportation, and licensed service site operation of psilocybin in the state.
	Considerations:
	• The officers and employees of the Field Enforcement Division shall enforce the provisions of this article relating to unlicensed commercial enterprise, including:
	  ○ Unlawful commercial importation or interstate trafficking of psilocybin.
	  ○ Unlicensed commercial-scale cultivation, extraction, processing, or synthesis of psilocybin outside a licensed cultivation facility.
	  ○ Operation of an unlicensed commercial storefront, "gifting" retail shop, or fee-for-service wellness facility offering psilocybin administration or facilitation for financial gain or remuneration.
	  ○ Unlicensed commercial retail distribution of psilocybin products, synthetic analogues, or misbranded functional equivalents to the public.
	• Except as expressly authorized under this article, a person or entity may not engage in commercial sale, commercially remunerated transfer, or retail marketing of psilocybin, psilocybin-containing fungi, or psilocybin derivatives.
	• The Field Enforcement Division is also authorized to investigate and refer to prosecution any transportation or distribution of peyote unrelated to the ceremonial use by the Native American Church authorized by the American Indian Religious Freedom Act Amendments of 1994.

• Law enforcement shall update DUI protocols with available testing methods for psychedelic impairment.	**See October 2025 Report, propositions:** 29b

LEGAL PROTECTIONS RELATED TO THE STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
Base Statutory Language	**Recommended Provisions**
• The Regulatory Authority shall ensure that veterans and first responders have convenient, low-cost treatment under this program if recommended by their health care provider.	
• Amend the Tax – General Article, Title 10, Income Tax, to provide that Maryland taxpayers engaged in business related to psilocybin should have the benefit of state income tax deductions for qualified business expenses that apply to other taxpayers.	**See October 2025 Report, propositions:** 53a
• Amend the Health Occupations Article, to provide that any person licensed or regulated by a Maryland health occupation board shall not be disciplined by such board for, in the course of their professional practice, engaging in administration of psilocybin in compliance with the regulations of the Medical Psilocybin Access Program.	**See October 2025 Report, propositions:** 82a
• Amend the Health Occupations Article, to require certain professions to report to the Regulatory Authority if the circumstances of a licensed psilocybin user have changed. State professional licensing boards for psychiatrists, psychologists and licensed clinical social workers shall require their licensed professionals to report to the Regulatory Authority if a patient or client is known to them to be a licensed user of psilocybin but in their training and judgement is at distinct risk of harm from use of psilocybin.	
• Amend the Insurance Article, the Health Occupations Article, and the Education Article to create a no-fault alternative to lawsuits alleging injury due to negligence or malpractice related to lawful administration of psilocybin by authorized health care providers or facilitators.	**Considerations:** • A no-fault alternative to lawsuits along the line of the statutorily-created Florida Birth-Related Neurological Injury Compensation Association (NICA).

LEGAL PROTECTIONS RELATED TO THE STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	See October 2025 Report, propositions: 83a, 39b
• Amend the Family Law Article to provide that personal use or possession of psilocybin, without evidence of other conduct or circumstances suggesting abuse or neglect, is not grounds for initiating a proceeding or sustaining a finding of child abuse or neglect.	**See October 2025 Report, propositions:** 8a
• Amend the Insurance Article, Education Article, State Government Article including Title 20, Subtitle 7 related to Housing Discrimination; Health General Article, Commercial Law Article related to credit and other transactions; the Labor and Employment Article, the Tax Property Article, etc., to protect from discrimination in employment, extension of credit, housing, health care, education or any other law bar discrimination to include among the classes of persons who are protected from discrimination, any person on the basis of their lawful use of psilocybin.	**See October 2025 Report, propositions:** 9b

PREPARATION IN ANTICIPATION OF FDA-APPROVED PSILOCYBIN MEDICINE	
Base Statutory Language	**Recommended Provisions**
● The Department of Health shall coordinate and manage state preparation for the delivery of FDA-approved psilocybin medicine, following FDA approval and required federal scheduling changes. ● The Department of Health shall consult with the relevant health occupations boards, including those for physicians, nursing, pharmacy, psychology, social work, and professional counseling. Together they shall identify and address State-level barriers to implementation, including barriers to implementing FDA-required Risk Evaluation and Mitigation Strategy (REMS). ● The Department of Health shall report to the Governor and General Assembly on or before July 1, 2027 on State readiness and any recommended legislative or regulatory changes necessary to provide FDA-approved psilocybin medicine. ● The Department of Health and relevant professional boards shall complete any necessary confirming changes recommended by the report no later than ninety (90) days following such federal rescheduling or ninety (90) days following submission of the report, whichever is later.	**Considerations:** ● The preparation planning shall address: ○ Identifying Facilities: capacity to meet certification, space, licensing, and monitoring requirements. ○ Workforce: staffing, training, and scope of practice for clinicians who prescribe, administer, or monitor treatment. ○ Patient safeguards: screening, informed consent, adverse-event reporting, and follow-up. ○ Affordable access: a review of Medicaid coverage, engagement with commercial insurers, and rural access. ○ Outcomes monitoring: establish systems to obtain and analyze data on use, outcomes, adverse events, and equity, coordinated with federal requirements and Maryland research institutions. ○ Clarity for patients and clinicians: plain-language guidance on how FDA-approved care differs from the state-regulated program. **See October 2025 Report, propositions:** 84a

CRIMINAL JUSTICE REFORM	
Base Statutory Language	**Recommended Provisions**
• All persons operating in compliance with this Act shall not be subject to discrimination nor criminal or civil penalties under Maryland law.	
• Amend the Criminal Procedure article to provide that a law enforcement officer may not initiate a stop or a search of a person, a motor vehicle, or a vessel based solely on: the possession of a personal use amount of psilocybin.	**Considerations:** • "Personal use amount" for this section means for a person 10 dosage packages from a licensed distributor of any state, or 10 grams of psilocybin mushroom in any form (i.e., whole, dry mushroom, powdered mushroom). **See <u>October 2025 Report</u>, propositions:** 24a
• It shall be the policy of the State of Maryland and all law enforcement agencies subject to its authority that the making of arrests for personal possession or cultivation for personal use of any natural psychedelic substance should be the lowest law enforcement priority.	**Considerations:** • Cultivation for personal use may be defined in terms of harvestable material, area devoted to cultivation, quantity possessed, etc. • Personal cultivators shall cultivate only unmodified, naturally occurring species to qualify for this policy. Personal cultivators shall not genetically modify or artificially enhance active substance levels. • Law enforcement is authorized to inspect personal cultivation sites and collect samples for testing to determine active substance levels and verify compliance with subsection. **See <u>October 2025 Report</u>, propositions:** 27a, 88
• Amend the Criminal Law Article, sections 5-601, 5-601.1 and 5-601.2 to provide that the simple possession and personal	**See <u>October 2025 Report</u>, propositions:** 31a

CRIMINAL JUSTICE REFORM	
cultivation of natural psychedelic substances outside of the circumstances or conditions authorized by the Regulatory Authority, shall be subject to citation and not criminal prosecution.	
• Amend the Criminal Law Article and the Criminal Procedure Article to provide that any person convicted of misdemeanor possession of natural psychedelic substance under the Criminal Law Article shall be able to have the conviction vacated and the record of the arrest and conviction shielded along the lines of SB 483 as enrolled in 2026.	**See October 2025 Report, propositions:** 33a, 86

REGULATORY AMENDMENTS	
Constitutionally Mandated Regulatory Amendment	**Recommended Provision**
• Secretary of Health shall amend COMAR Section 10.19.03.04A	• Add a new clause: "(7) Manufactures a natural psychedelic substance for, or distributes a natural psychedelic substance to, any church or religious or spiritual community, or member or participant thereof, for bona fide religious ceremonies of that church or religious or spiritual community." **See October 2025 Report, propositions:** 59a

IMPLEMENTATION TIMELINE FOR THE STATE-REGULATED MEDICAL PSILOCYBIN ACCESS PROGRAM	
	• Psychedelic Substances Advisory Board shall be established. • Regulatory Authority for the state-regulated Medical Psilocybin Access Program shall be established.
No later than January 1, 2028	• The Regulatory Authority shall promulgate rules and regulations for the program. • Legal Protections shall take effect. • Criminal Justice Reform shall take effect.
No later than April 1, 2028	• Licensing applications shall open for the program.
No later than July 1, 2028	• Licensed entities may begin operations. • Enforcement of the program shall take effect.

Program Funding and Fiscal Impact

If the Maryland Cannabis Administration is designated as the regulatory authority for the state-regulated Medical Psilocybin Access Program, its statutory Cannabis Regulation Enforcement Fund should be amended to cover initial startup expenses, thereby financing the program without relying on Maryland's general fund.

Within the Task Force's prior **October 2025 Report**, **Appendix 6** **featured an independent analysis by economists at Johns Hopkins University**, which assessed the potential economic and social impacts of a state-regulatory framework.This analysis highlights several key economic factors relevant to preparing a fiscal note:

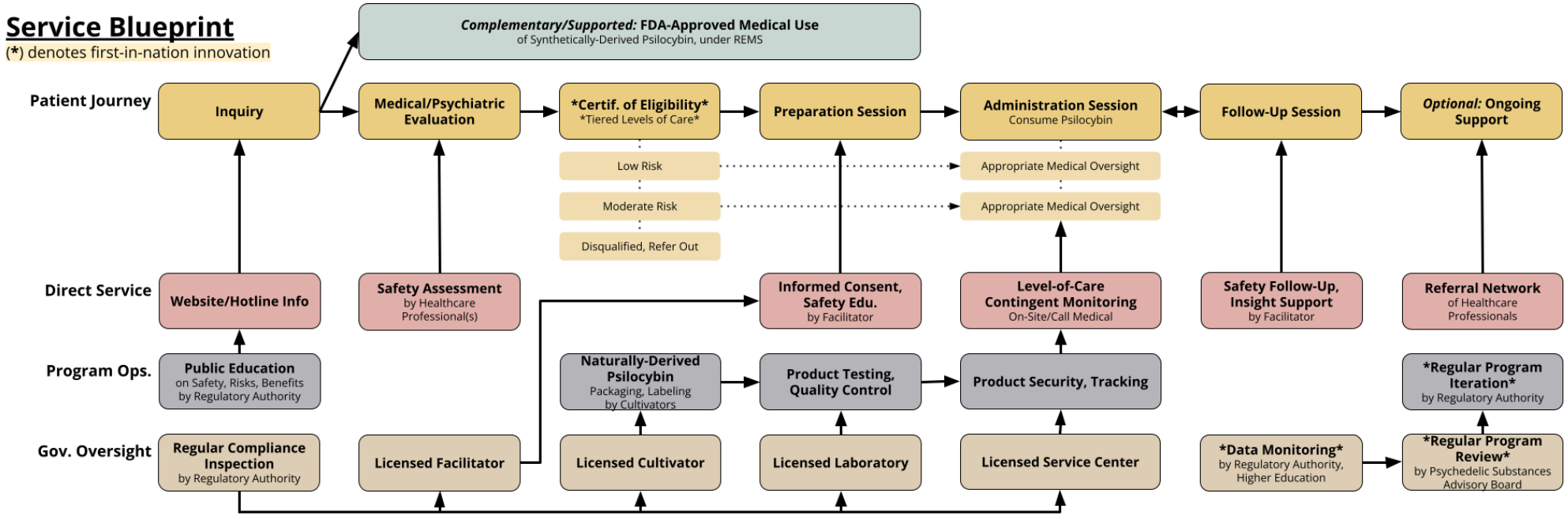
- Direct and indirect state income: Licensing fees, sales tax, etc.
- Indirect state income: Economic growth, workplace productivity, etc.
- State cost savings: Reduced healthcare costs, etc.
- Program cost-reduction levers: Right-sizing training, scaling psychotherapy, etc.
- Market Expectations: Estimated patients per year, projected annual spending, etc.

An updated, comprehensive, independent analysis from economists at Johns Hopkins University is anticipated.

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Appendix 1. Service Blueprint for State-Regulated Program



Appendix 2. Task Force's Anticipated Issue Briefs

The Task Force on Responsible Use of Natural Psychedelic Substances is drafting the following Issue Briefs, anticipated to be published to the Department of Legislative Services by the end of 2026:

- Federal and Nationwide Policy Updates
- How Psychedelics Work
- Ibogaine
- Task Force Activity

Once published, Issue Briefs will be available via the Department of Legislative Services library, Maryland Cannabis Administration website, and Task Force member-hosted website MarylandNPS.org.

Appendix 3. Features Across State-Regulated Programs

	Oregon (est. 2021)	Colorado (est. 2022)	New Mexico (est. 2025)	Maryland (Recommended)
Substances and Production				
Psilocybin Only	☑️ Yes	❌ No	☑️ Yes	✅ Yes
Production by Licensed Entities	☑️ Yes	☑️ Yes	☑️ Yes	✅ Yes
Production by Personal Cultivation	❌ No	☑️ Yes	❌ No	❌ No
Regulated Access Breadth				
Regulated Clinical Use (Medical Diagnosis)	☑️ Yes	☑️ Yes	☑️ Yes	✅ Yes
Regulated Well-Being Use (Extraclinical)	☑️ Yes	☑️ Yes	❌ No	❓ Pending Data Monitoring and Review
Regulated Spiritual Use	☑️ Yes	☑️ Yes	❌ No	❓ Pending Data Monitoring and Review
Regulated Adult Use	☑️ Yes	☑️ Yes	❌ No	❓ Pending Data Monitoring and Review
Clinical Use - Professional Oversight				
Prerequisite Screening by Medical Professionals	❌ No	❌ No	☑️ Yes	✅ Yes
Supervision Required During Administration	☑️ Yes	❌ No	☑️ Yes	✅ Yes
Supervision Requirements Tiered (Reduced Costs + Increased Accessibility)	❌ No	❌ No	❌ No	✅ *Yes (innovation)*
Facilitator License Restricted to Medical Professionals	❌ No	❌ No	☑️ Yes	❌ No
Facilitator License Allows Medical Professionals	❌ No, Dual-Practice Prohibited	☑️ Yes	☑️ Yes	✅ Yes, Pending State Boards
State-Led General-Public Education	❌ No	☑️ Yes	❌ No	✅ Yes
Data Monitoring and Program Iteration				
Monitoring Individual Outcomes upon Launch	❌ No	❌ No	☑️ Yes	✅ Yes
Monitoring Population-Level Outcomes upon Launch	❌ No	❌ No	❌ No	✅ *Yes (innovation)*
Mechanisms for Program Iteration upon Launch	❌ No	❌ No	☑️ Yes	✅ Yes
Criminal Justice Reform				
Reduced Penalties for Personal Possession	❌ No	☑️ Yes	❌ No	✅ Yes
Reduced Penalties for Personal Cultivation	❌ No	☑️ Yes	❌ No	✅ Yes

Appendix 4. State-Regulated Program Supporting FDA-Approval

	Standalone State-Regulated Program	Standalone FDA-Approved Medicine	Complementary: State-Regulated Program Supporting FDA-Approval
Substance Scope			
Naturally-Derived Whole Mushroom	✅ Yes	❌ No	✅☑️ Both Naturally and Synthetically Derived are Regulated
Proprietary Synthetic Derivative	❌ No	☑️ Yes	
Regulated Access and Market			
Access Restricted to Certain Healthcare Facilities	❌ No	☑️ Yes	✅☑️ Multiple Access Location Types
Access in Service Centers/Sites	✅ Yes	❌ No	
Regulated/Safe Clinical Use (Medical Diagnosis, higher-risk population)	✅ Yes	☑️ Yes	✅☑️ All Identified Psilocybin Uses are Regulated, Out-Competing Illicit Market with New Industry
Regulated/Safe Well-Being Use (Extraclinical, lower-risk population)	✅ Yes	❌ No	
Regulated/Safe Spiritual Use	✅ Yes	❌ No	
Regulated/Safe Adult Use	✅ Yes	❌ No	
Deterring Illicit Markets	✅ Yes	❌ No	
Creation of New Industry	✅ Yes	❌ No	
Protection in Federal Law	❌ No	☑️ Yes	☑️ Legal and Potential Insurance Coverage for Clinical Use (Medical Diagnosis)
Potential Insurance Coverage	❓ Pending Maryland General Assembly direction to Maryland insurance regulators	☑️ Yes	
Implementation Readiness	❓ Exploratory	❓ Pre-Operational	
Social Impact			
Reparative Justice (equitable licensing, expungement, etc.)	✅ Yes	❌ No	✅ Reparative Justice
Education for Patients	✅ Yes	☑️ Yes	✅☑️ Comprehensive Public Education
Education for General-Public	✅ Yes	❌ No	
Oversight			
Maryland-Specific Data Monitoring (ER visits, DUI, days off work, etc.)	✅ Yes	❌ No	✅ Maryland-Tailored Safety Standards, Responsive to Maryland-Data
Maryland-Tailored Safety Standards	✅ Yes	❌ No	
Responsive/Adaptable Safety Standards	✅ Yes	❌ No	